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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,985	01/16/2004	Raymond F. Schinazi	EMU133 CON 5 18085.105302	8318
7590 01/25/2006			EXAMINER	
Sherry M. Knowles 45th Floor 191 Peachtree Street, N.E. Atlanta, GA 30303			CRANE, LAWRENCE E	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,985

Applicant(s)

SCHINAZI ET AL.

Examiner

L. E. Crane

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/16/2004 (preliminary amdt).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 14-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 14-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/16/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims **1-11 and 13** have been cancelled, claims **12** has been amended, the disclosure has been amended at page 1, and new claims **14-33*** have been added as per the preliminary amendment filed with the instant application. One Information Disclosure Statement (1 IDS) filed January 16, 2004 has been received with copies of all newly cited references and made of record.

* Applicant has mistakenly numbered two claims as "claim 32." Under the authority of 37 CFR §1.126, the claims have been renumbered as ending in claim **33** (second claim **32** is now claim **33**). Applicant is respectfully requested to correct all future communications to reflect this change.

Note to applicant: Because of the failure to date of the PTO to copy paper files of parent cases, applicant is advised that one way the vast majority of reference citations will be made of record in the scanned document database for this application would be for applicant to submit copies of same for scanning.

Claims **12 and 14-33** remain in the case.

The disclosure is objected to because of the following informalities:

The page displaying Table 3 and Table 4 appears to have been intended to be "page 28," but said page does not have a page number.

Appropriate correction is required.

Claims **12 and 14-33** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **12** at line 3 the term "an HIV related opportunistic infectious disease" is generic and is not accompanied in the instant claim by any listing of all such infections which are intended to be treated, thereby rendering the instant claim incompletely defined. See also claim **16** wherein the same term also appears.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **12 and 14-33** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-10** of U.S. Patent No. **6,680,303** (PTO-892 ref. **G**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment of HIV and the alleged active ingredients are directed to substantially overlapping subject matter because the instant claims are directed to a method of treating diseases which only occur when HIV has compromised the immune system, a condition which nucleoside analogues are well known to be capable of reversing by suppressing HIV and thereby permitting immune function to be reestablished.

Claim **12 and 14-33** is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-10** of U.S. Patent No. **6,391,859** (PTO-892 ref. **A**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment of HIV and the alleged active ingredients are directed to substantially overlapping subject matter because the instant claims are directed to a method of treating diseases which only occur when HIV has compromised the immune system, a condition which nucleoside analogues are well known to be capable of reversing by suppressing HIV and thereby permitting immune function to be reestablished.

Claim **12 and 14-33** is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-10** of U.S. Patent No. **6,232,300** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment of HIV and the alleged active ingredients are directed to substantially overlapping subject matter because the instant claims are directed to a method of treating diseases which only occur when HIV has compromised the immune system, a condition which nucleoside analogues are well known to be capable of reversing by suppressing HIV and thereby permitting immune function to be reestablished.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

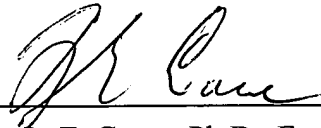
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

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LECrane:lec
01/16/2006

A handwritten signature in cursive script, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.

Patent Examiner

Technology Center 1600